AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Majeed *et al.*

Confirmation No. 2480

Group Art Unit: 1617

Application Serial No.: 09/926,424

Examiner: Jiang, S.A.

Filed: July 28, 2002

Attorney Docket No.: 108064-00049

For: Compositions of Boswellic Acids Derived from *Boswellia serrata* Gum Resin for Treating Lymphoproliferative and Autoimmune Conditions

August 16, 2004

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APPEAL BRIEF TRANSMITTAL

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Sir:

Pursuant to 37 C.F.R. §1.17(c), the applicants enclose a check in the amount of Three Hundred and Thirty Dollars ($330.00) to cover the official fee for the filing of this Appeal Brief (filed in triplicate). In the event this brief is not timely filed, the applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 108064-00049.

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THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of:

Majeed *et al.*	Group Art Unit: 1617
Application Serial No.: 09/926,424	Examiner: Jiang, S.A.
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For: Compositions of Boswellic Acids Derived from *Boswellia serrata* Gum Resin for Treating Lymphoproliferative and Autoimmune Conditions

BRIEF ON APPEAL

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TABLE OF CONTENTS

I. INTRODUCTION

This is an appeal from a final official action dated December 16, 2003, wherein the pending claims were rejected under 35 U.SC. §§112 and 103. The claim rejections were affirmed in an Advisory Action dated April 20, 2004.

II. REAL PARTY IN INTEREST

The real part in interest is Sabinsa Corporation as evidenced by the assignment recorded at the United States Patent and Trademark Office on June 28, 2002 at Reel 013167, Frame 0872.

III. RELATED APPEALS AND INTERFERENCES

The appellants, appellant's legal representative, or assignee are not aware of any related appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

IV. STATUS OF CLAIMS

Claims 148 to 151, 175, and 177 to 191 are finally rejected and are under appeal. Claims 1 to 147, 152 to 174, and 176 were canceled. A copy of the claims under appeal can be found in the Appendix.

V. STATUS OF AMENDMENTS

The appellants filed a response under 37 C.F.R. §1.116 on March 16, 2004. This response was accompanied by a declaration under 37 C.F.R. §1.132 by one of the inventors, Dr. Vladimir Badmaev. The examiner issued an Advisory Action dated April 20, 2004. While it would appear that the examiner may have considered the appellants' request for reconsideration, it is not clear whether the appellants' response or the declaration by Dr. Badmaev was entered (the examiner did not check either box on the Advisory Action coversheet to indicate whether the response and declaration were, or were not, entered). In the Advisory Action, the examiner did, however, reaffirm the rejection of claims 148 to 151, 175, and 177 to 191.

VI. SUMMARY OF THE INVENTION

The present invention relates to new compositions of four purified boswellic acids (β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid, and acetyl-11-keto-β-boswellic acid) that individually or in mixtures, have been found effective in treating lymphoproliferative and autoimmune diseases (page 2, line 2 to page 3, line 9). The specification of the invention contains figures showing the effects of the four boswellic acids on DNA, RNA, and protein syntheses in HL-60 cells (Figures 1 to 4). The invention is claimed as described next.

A. Claim 148

Independent claim 148 is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

B. Claim 149

Additional features of the invention can be found in claim 149, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 12% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

C. Claim 150

Additional features of the invention can be found in claim 150, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 12 to 35% by weight, acetyl-β-boswellic acid of at least 5 to 35% by weight, 11-keto-β-boswellic acid of at least 15 to 45% by weight and acetyl-11-keto-β-boswellic acid of at least 14 to 45% by weight.

D. Claim 151

Additional features of the invention can be found in claim 151, which is directed to a method for the treatment of psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

E. Claim 175

Independent claim 175 is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising acetyl-11-keto-β-boswellic acid.

F. Claim 177

Additional features of the invention can be found in claim 177, which is directed to a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

G. Claim 178

Additional features of the invention can be found in claim 178, which is directed to a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising acetyl-11-keto-β-boswellic acid.

H. Claim 179

Independent claim 179 is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition.

I. Claim 180

Additional features of the invention can be found in claim 180, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 55% by weight, acetyl-β-boswellic acid of 10 to 55% by weight, 11-keto-β-boswellic acid of 5 to 50% by weight and acetyl-11-keto-β-boswellic acid of 5 to 50% by weight.

J. Claim 181

Additional features of the invention can be found in claim 181, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 35% by weight, acetyl-β-boswellic acid of 10 to 35% by weight, 11-keto-β-boswellic acid of 5 to 40% by weight and acetyl-11-keto-β-boswellic acid of 5 to 40% by weight.

K. Claim 182

Additional features of the invention can be found in claim 182, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by

weight, acetyl-β-boswellic acid of 5% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 60% by weight.

L. Claim 183

Additional features of the invention can be found in claim 183, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 50% by weight.

M. Claim 184

Additional features of the invention can be found in claim 184, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 40% by weight.

N. Claim 185

Additional features of the invention can be found in claim 185, which is directed to a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition.

O. Claim 186

Additional features of the invention can be found in claim 186, which is directed to a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids

selected from the group consisting of: β-boswellic acid of 14 to 55% by weight, acetyl-β-boswellic acid of 10 to 55% by weight, 11-keto-β-boswellic acid of 5 to 50% by weight and acetyl-11-keto-β-boswellic acid of 5 to 50% by weight.

P. Claim 187

Additional features of the invention can be found in claim 187, which is directed to a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 35% by weight, acetyl-β-boswellic acid of 10 to 35% by weight, 11-keto-β-boswellic acid of 5 to 40% by weight and acetyl-11-keto-β-boswellic acid of 5 to 40% by weight.

Q. Claim 188

Additional features of the invention can be found in claim 188, which is directed to a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 5% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 60% by weight.

R. Claim 189

Additional features of the invention can be found in claim 189, which is directed to a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 50% by weight.

S. Claim 190

Additional features of the invention can be found in claim 190, which is directed to a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three

boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 40% by weight.

T. Claim 191

Additional features of the invention can be found in claim 191, which is directed to a method for the treatment of psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition.

VII. ISSUES

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification. Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nagasawa *et al.* (JP 04-288095) in view of Shao *et al.* (*Planta Med.* **64(4)**, 328 - 331, 1998). Finally, claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Taneja *et al.* (EP 0 755 940) in view of Shao *et al.*

Therefore, the issues in this appeal are whether claims 148 to 151, 175, and 177 to 191 are adequately supported by the specification under 35 U.S.C. §112, first paragraph and whether claims 148 to 151, 175, and 177 to 191 are patentable under 35 U.S.C. §103(a) over Nagasawa *et al.* in view of Shao *et al.* and over Taneja *et al.* in view of Shao *et al.*

VIII. GROUPING OF THE CLAIMS

For purposes of appeal, the claims may be grouped as follows:

Group I: Claims 148 to 151, 175, and 177 to 191

The claims do not stand or fall together and are argued individually in the following section.

IX. ARGUMENT

A. Rejection Under 35 U.S.C. §112, First Paragraph:

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification.

B. The Law Regarding 35 U.S.C. §112, First Paragraph:

During the evaluation of the requirements under 35 U.S.C. §112, first paragraph, the Court in *In re Wertheim*, 191 USPQ 90 (CCPA 1976) held that "(t)he primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *Wertheim*, 191 USPQ at 91 (emphasis in original). In *Wertheim*, the appellants had provided a description of the invention as employing solids content within the range of 25% to 60% along with specific embodiments of 36% and 50%. They were claiming a solids content ranging from between 35% and 60%. The Court found that on the basis of two specific examples, the appellants were entitled to a range of 35% to 60%.

In the present application, the examiner alleges that the "original specification provides no disclosure and working examples for particular compositions comprising the boswellic acids herein with the particular amount, the instant single point of percentage, for each boswellic acid recited in the claims herein." (Final official action dated December 16, 2003, page 3, emphasis in the original). This allegation has absolutely no basis in fact. The specification as filed provides explicit support for the ranges of several claims. The specification lists no fewer than 30 compositions describing various ranges and point percentages of compositions comprising four, three, and two boswellic acids (see, for example, the specification as filed, pages 17 to 21).

With respect to the claims directed to point percentages, the issue is whether the specification as filed provides sufficient disclosure to one of ordinary skill in the art. It is important to note that the specification as filed provides support for a composition comprising at least 5% by weight of β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid and acetyl-11-keto-β-boswellic acid (page 18, lines 1 to 8). In other words, this disclosure is sufficient to provide support for every point above 5%.

The examiner's allegation of lack of support has absolutely no basis in law either. In a manner similar to that in *Wertheim*, "(t)he PTO has done nothing more than to argue lack of literal support, which is not enough." *Wertheim*, 191 USPQ at 91. Therefore the appellants respectfully submit that the disclosure provides sufficient disclosure to one of ordinary skill in the art for both the ranges and point percentages claimed.

The examiner cites *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111 (CAFC 1991) and *In re Winkhaus*, 188 USPQ 129 (CCPA 1975) in support of her position and further alleges that the last set of amendments to the claims introduce new matter.

Vas-Cath v. Mahurkar deals with whether drawings in a prior design application provide sufficient written description under 35 U.S.C. §112, first paragraph, for the utility application under appeal, which the Court found they did. It is unclear what, if anything, this case has to do with the present application considering that the present application is not claiming priority to a design application. In addition, the appellants are not using any drawings in the present application nor the parent application for written description purposes. If anything, this case furthers the appellants' argument in the present application because it shows that the specification need not provide *ipsis verbis* support for claims.

In re Winkhaus, the appellant, faced with a rejection of the claims under 35 U.S.C. §132, admitted that the specification as filed did not disclose a specific feature but argued that sufficient disclosure could be found and would be obvious upon reading their specification. *Winkhaus*, 188 USPQ at 130. Unlike the appellants in *Winkhaus*, the current appellants do not admit that the specification as filed does not explicitly disclose specific percentages. Indeed, the appellants have argued and shown quite the

opposite, namely that the specification not only provides specific support for almost all the point percentages, but also implicitly does so for the remainder in accordance with *Wertheim*. It is also improper for the examiner to set forth any "new matter" rejection because *Wertheim* makes clear that the specification provides sufficient written description and enablement for all the claims currently pending.

In conclusion, the examiner has misapplied the cases she cited and clearly has not contemplated the liberal written description requirement of *Wertheim*. Further, the appellants' claims directed to specific point percentages within these ranges is not "new matter". As shown next, the specification fully supports each of the claims under 35 U.S.C. §112.

1. Claim 148 is Fully Supported Under 35 U.S.C. §112

Claim 148 is directed to, *inter alia,* a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 148 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

2. Claim 149 is Fully Supported Under 35 U.S.C. §112

Claim 149 is directed to, *inter alia,* a composition comprising: β-boswellic acid of at least 12% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 149 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

3. Claim 150 is Fully Supported Under 35 U.S.C. §112

Claim 150 is directed to, *inter alia,* a composition comprising: β-boswellic acid of at least 12 to 35% by weight, acetyl-β-boswellic acid of at least 5 to 35% by weight, 11-keto-β-boswellic acid of at least 15 to 45% by weight and acetyl-11-keto-β-boswellic acid of at least 14 to 45% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 150 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

4. Claim 151 is Fully Supported Under 35 U.S.C. §112

Claim 150 is directed to a method for the treatment of psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 151 can be found in the specification on page 5, line 17 to page 6, line 2, and page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

5. Claim 175 is Fully Supported Under 35 U.S.C. §112

Claim 175 is directed to, *inter alia,* a composition comprising acetyl-11-keto-β-boswellic acid.

As found by the Court in *Wertheim*, sufficient support for claim 175 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

6. Claim 177 is Fully Supported Under 35 U.S.C. §112

Claim 177 is directed to, *inter alia,* a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 177 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

7. Claim 178 is Fully Supported Under 35 U.S.C. §112

Claim 178 is directed to, *inter alia,* a composition comprising acetyl-11-keto-β-boswellic acid.

As found by the Court in *Wertheim*, sufficient support for claim 178 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

8. Claim 179 is Fully Supported Under 35 U.S.C. §112

Claim 179 is directed to, *inter alia*, a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein said subject is a human or animal, and wherein the % by weight is based on the total weight of the composition.

Support for the specific ranges of the three boswellic acid compositions claimed in claim 179 can be found on page 18, lines 8 to 18. Therefore, the appellants respectfully submit that claim 179 is fully supported under 35 U.S.C. §112.

9. Claim 180 is Fully Supported Under 35 U.S.C. §112

Claim 180 is directed to, *inter alia*, a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 55% by weight,

acetyl-β-boswellic acid of 10 to 55% by weight, 11-keto-β-boswellic acid of 5 to 50% by weight, and acetyl-11-keto-β-boswellic acid of 5 to 50% by weight.

Support for the specific ranges of the three boswellic acid compositions claimed in claim 180 can be found on page 18, lines 8 to 18. Therefore, the appellants respectfully submit that claim 180 is fully supported under 35 U.S.C. §112.

10. Claim 181 is Fully Supported Under 35 U.S.C. §112

Claim 181 is directed to, *inter alia*, a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 35% by weight, acetyl-β-boswellic acid of 10 to 35% by weight, 11-keto-β-boswellic acid of 5 to 40% by weight, and acetyl-11-keto-β-boswellic acid of 5 to 40% by weight.

Support for the specific ranges of the three boswellic acid compositions claimed in claim 181 can be found on page 18, lines 8 to 18. Therefore, the appellants respectfully submit that claim 181 is fully supported under 35 U.S.C. §112.

11. Claim 182 is Fully Supported Under 35 U.S.C. §112

Claim 182 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 5% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 60% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 182 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

12. Claim 183 is Fully Supported Under 35 U.S.C. §112

Claim 183 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 50% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 183 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

13. Claim 184 is Fully Supported Under 35 U.S.C. §112

Claim 184 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 40% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 184 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

14. Claim 185 is Fully Supported Under 35 U.S.C. §112

Claim 185 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition.

As found by the Court in *Wertheim*, sufficient support for claim 185 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

15. Claim 186 is Fully Supported Under 35 U.S.C. §112

Claim 186 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 55% by weight, acetyl-β-boswellic acid of 10 to 55% by weight, 11-keto-β-boswellic acid of 5 to 50% by weight and acetyl-11-keto-β-boswellic acid of 5 to 50% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 186 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

16. Claim 187 is Fully Supported Under 35 U.S.C. §112

Claim 187 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 35% by weight, acetyl-β-boswellic acid of 10 to 35% by weight, 11-keto-β-boswellic acid of 5 to 40% by weight and acetyl-11-keto-β-boswellic acid of 5 to 40% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 187 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

17. Claim 188 is Fully Supported Under 35 U.S.C. §112

Claim 188 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 5% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 60% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 188 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

18. Claim 189 is Fully Supported Under 35 U.S.C. §112

Claim 189 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 50% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 189 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

19. Claim 190 is Fully Supported Under 35 U.S.C. §112

Claim 190 is directed to, *inter alia,* a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-

β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 40% by weight.

As found by the Court in *Wertheim*, sufficient support for claim 190 can be found in the specification on page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

20. Claim 191 is Fully Supported Under 35 U.S.C. §112

Claim 191 is directed to a method for the treatment of psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition.

As found by the Court in *Wertheim*, sufficient support for claim 191 can be found in the specification on page 5, line 17 to page 6, line 2 and page 17, line 1 to page 20, line 24. Therefore, the appellants respectfully submit that claim 148 is fully supported under 35 U.S.C. §112.

C. Rejections under 35 U.S.C. §103(a)

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nagasawa *et al.* (JP 04-288095) in view of Shao *et al.* (*Planta Med.* **64(4)**, 328 - 331, 1998). Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Taneja *et al.* (EP 0 755 940) in view of Shao *et al.*

D. The Law Regarding 35 U.S.C. §103(a)

In *Graham v. John Deere Co.*, 148 USPQ 459 (1966), the Supreme Court set forth the standard for patentability for non-obvious subject matter. "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham*, 148 USPQ at 467. The Manual of Patent Examining Procedure (M.P.E.P.) clearly instructs examiners "(w)hen applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined." (M.P.E.P. §2141, emphasis added).

However, the M.P.E.P. cautions that, "(b)efore answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. §102. *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1597" (CAFC 1987) (M.P.E.P. §2141.01, emphasis added). An "(a)pplicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. §102(a). *In re Katz*, 215 USPQ 14 (CCPA 1982) (discussed below). Therefore, where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. *Ex parte Hirschler*, 110 USPQ 384 (Bd. App. 1952). The rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing the applicant's own work. *In re Katz*. However, if there is evidence that the co-author has refused to disclaim inventorship and believes himself or herself to be an inventor, applicant's affidavit will not be enough to establish

that applicant is the sole inventor and the rejection will stand. *Ex parte Kroger*, 219 USPQ 370 (Bd. Pat. App. & Int. 1982)." (M.P.E.P. §2132.01, emphasis added).

In *Katz*, the examiner in that application stated that "there is no evidence of record which makes it clear that appellant is the sole inventor of the claimed subject matter. Where a reference is from a collection of authors, it must be assumed that all authors contributed equally..." *Katz*, 215 USPQ at 16. Upon appeal, the Court reversed the claim rejections under 35 U.S.C. §102(a). The Court held that authorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed and co-authors may not be presumed to be co-inventors merely from the fact of co-authorship. *Katz*, 215 USPQ at 18 (emphasis added).

The Court also specifically addressed sufficiency of the declaration filed by Dr. David H. Katz and the requirement for additional evidence. In the declaration, the appellant, Dr. Katz, explained that the co-authors of the publication were students working under the direction and supervision of the inventor. The Court concluded that the appellant's declaration was sufficient to overcome the rejection and that no additional evidence (*e.g.*, in the form of disclaiming affidavits or declarations) was required. *Katz*, 215 USPQ at 18 (emphasis added).

The present application is a continuation of, and claims priority to, U.S. Pat. Appl. Ser. No. 09/302,510, filed April 30, 1999. The appellants filed a declaration under 35 U.S.C. §1.132 by Dr. Muhammed Majeed and Dr. Vladimir Badmaev stating that Shao *et al.*, published in May 1998, contained the applicant's own work. During prosecution of the parent application the examiner rejected the declaration by Drs. Majeed and Badmaev by stating that:

- "The declaration of Muhammed Majeed and Vladimir Badmaev lacks facts as documentary evidence, e.g., notebooks, photographs, or drawings to prove the conception derived from them alone, not from Shao, Ho, Chin, Ma, and Huang, especially Professor Chi-Tang Ho who is the major author for this cited reference."
- "Further, the statement in this declaration, 'the other authors of the literature reference Shao Y, Ho CT, Chin CK, Ma W, and Huang MT were contracted by us to

perform experiments described in the report' is a totally unsupported statement." (Final official action dated February 12, 2002, page 8).

First, the law does not require the appellants to provide any additional evidence regarding inventorship (see *In re Katz*). Therefore, the examiner is clearly not following the law by dismissing the declaration on the grounds that it does not contain documentary evidence. Second, the examiner has provided no evidence to support her opinion that Professor Chi-Tang Ho is the major author for Shao *et al.* or that the other co-authors are also co-inventors. Indeed, neither U.S. patent procedure, nor U.S. statute, nor even U.S. case law gives the examiner any authority to question the appellants' declarations filed in accordance with the ruling in *In re Katz*.

A necessary precondition for any such inquiry is evidence that the co-author has refused to disclaim inventorship and believes himself or herself to be an inventor (see *Ex parte Kroger*). The examiner has provided no such evidence and obdurately insists that the declarations are insufficient (see the Advisory Action). The examiner also continues to insist on the appellants' providing documentary evidence to support the appellants' declarations. It is important to note that the appellants may, but are not required to, provide disclaiming affidavits (per *Ex parte Hirschler*). The examiner is flouting the law by continuing to reject the declarations, insist on documentary evidence, and maintain rejections based on Shao *et al.*

The appellants have, however, declared, affirmed, and reaffirm here that that Dr. Badmaev is a co-author of Shao *et al.* and that he is the sole inventor of the subject matter described therein, which is now claimed in the present application. The remaining co-authors, Y. Shao, C.T. Ho, C.K. Chin, W. Ma, and M.T. Huang, were merely working under the direction of Dr. Badmaev. None of the other co-authors of Shao *et al.* are inventors in the present application. Dr. Majeed is appropriately named as a co-inventor in the present application since the subject matter not coming from Shao *et al.* contains the contribution of Dr. Majeed.

In other words, Shao *et al.* is not an invention "by others" under 35 U.S.C. §102 and is not available as a reference under 35 U.S.C. §102. A reference that is not available under 35 U.S.C. §102 cannot be used in a rejection under 35 U.S.C. §103.

Since Shao *et al.* is not a reference available to the examiner, all the rejections relying on this reference are *per se* improper and should be withdrawn.

1. Claim 148 is Patentable Under 35 U.S.C. §103(a)

Claim 148 was rejected under 35 U.S.C. §103(a) over Nagasawa *et al.* in view of Shao *et al.* and over Taneja *et al.* in view of Shao *et al.* The unavailability of Shao *et al.* as a reference upon which the examiner can lawfully base a rejection leaves Nagasawa *et al.* and Taneja *et al.*

Nagasawa *et al.* merely describe a method for extracting β-boswellic acids from a mastic using petroleum ether. The ether extract is purified using silica-gel chromatography. In other words, Nagasawa *et al.* describe standard organic chemistry extraction and purification techniques. How could one of ordinary skill in the art using just Nagasawa *et al.*, reasonably be expected to obtain a method for treating autoimmune diseases with specific and effective amounts of the β-boswellic acids? Indeed the examiner herself repeatedly admits that Nagasawa *et al.* does not expressly disclose the effective amounts of β-boswellic acids useful in treating autoimmune diseases (see, for example, first official action dated July 28, 2003, page 6, paragraph 3). Therefore, she is forced to issue a rejection under 35 U.S.C. §103 (rather than under 35 U.S.C. §102) and attempt to overcome the deficiency in Nagasawa *et al.* by using Shao *et al.*

Taneja *et al.* disclose that six boswellic acid compounds (which include the four boswellic acids of the present invention) have anti-inflammatory, anti-arthritic, and anti-ulcerogenic activities. Importantly, they note that "(t)hough individual Boswellic acids of the formulae 1 to 5 have been isolated, it is our novel finding according to the present invention that the fraction containing the mixture of boswellic acids of the formulae 1 to 6 together with the unidentified compounds in the above said combination show synergistic combined anti-inflammatory, anti-arthritic and anti-ulcerogenic activities which is hitherto unknown." (page 4, lines 31 to 35, emphasis added).

In other words, not only do Taneja *et al.* not make any mention of autoimmune diseases, but they also clearly disclose that an extract containing a mixture of all six boswellic acids, along with some unknown compounds, has anti-inflammatory, anti-

arthritic, and anti-ulcerogenic activities. In contrast, the appellants' claimed invention is a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a four or fewer, specific, boswellic acids.

The appellants have also clearly shown using dictionary definitions that inflammation and autoimmune diseases are two different health disorders. The examiner blithely asserted that "one of ordinary skill in the art would recognize that autoimmune diseases broadly encompass inflammatory diseases." Not only has the examiner provided not one iota of evidence that one of ordinary skill in the art would view autoimmune diseases as broadly encompassing inflammatory diseases but *if* one of ordinary skill in the art would place inflammatory diseases within the category of autoimmune diseases, a quick review of Stedman's Medical Dictionary would rectify this fallacy.

Therefore, one of ordinary skill in the art reviewing the disclosure of Taneja *et al.* would understand that the combination of all six boswellic acids and other unknowns are have anti-inflammatory, anti-arthritic and anti-ulcerogenic activities. Taneja *et al.* neither teach, nor fairly suggest, specific compositions comprising four, three, two, or one of β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid, and acetyl-11-keto-β-boswellic acid in a method for the treatment of an autoimmune disease in a human or animal. Once again the examiner attempted to overcome the deficiency in Taneja *et al.* by using Shao *et al.*

To conclude, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight, as claimed in claim 148.

2. Claim 149 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective

amount of a composition comprising: β-boswellic acid of at least 12% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight, as claimed in claim 149.

3. Claim 150 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 12 to 35% by weight, acetyl-β-boswellic acid of at least 5 to 35% by weight, 11-keto-β-boswellic acid of at least 15 to 45% by weight and acetyl-11-keto-β-boswellic acid of at least 14 to 45% by weight, as claimed in claim 150.

4. Claim 151 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma in a human or animal, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight, as claimed in claim 151.

5. Claim 175 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective

amount of a composition comprising acetyl-11-keto-β-boswellic acid, as claimed in claim 175.

6. Claim 177 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising: β-boswellic acid of at least 5% by weight, acetyl-β-boswellic acid of at least 5% by weight, 11-keto-β-boswellic acid of at least 15% by weight and acetyl-11-keto-β-boswellic acid of at least 14% by weight, as claimed in claim 177.

7. Claim 178 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising acetyl-11-keto-β-boswellic acid, as claimed in claim 178.

8. Claim 179 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition, as claimed in claim 179.

9. Claim 180 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group

consisting of: β-boswellic acid of 14 to 55% by weight, acetyl-β-boswellic acid of 10 to 55% by weight, 11-keto-β-boswellic acid of 5 to 50% by weight and acetyl-11-keto-β-boswellic acid of 5 to 50% by weight, as claimed in claim 180.

10. Claim 181 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 35% by weight, acetyl-β-boswellic acid of 10 to 35% by weight, 11-keto-β-boswellic acid of 5 to 40% by weight and acetyl-11-keto-β-boswellic acid of 5 to 40% by weight, as claimed in claim 181.

11. Claim 182 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 5% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 60% by weight, as claimed in claim 182.

12. Claim 183 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 50% by weight, as claimed in claim 183.

13. Claim 184 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 40% by weight, as claimed in claim 184.

14. Claim 185 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition, as claimed in claim 185.

15. Claim 186 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 55% by weight, acetyl-β-boswellic acid of 10 to 55% by weight, 11-keto-β-boswellic acid of 5 to 50% by weight and acetyl-11-keto-β-boswellic acid of 5 to 50% by weight, as claimed in claim 186.

16. Claim 187 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of

an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 35% by weight, acetyl-β-boswellic acid of 10 to 35% by weight, 11-keto-β-boswellic acid of 5 to 40% by weight and acetyl-11-keto-β-boswellic acid of 5 to 40% by weight, as claimed in claim 187.

17. Claim 188 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 5% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 60% by weight, as claimed in claim 188.

18. Claim 189 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 50% by weight, as claimed in claim 189.

19. Claim 190 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of an autoimmune disease in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14% by weight, acetyl-β-boswellic acid of 10% by

weight, 11-keto-β-boswellic acid of 5% by weight and acetyl-11-keto-β-boswellic acid of 40% by weight, as claimed in claim 190.

20. Claim 191 is Patentable Under 35 U.S.C. §103(a)

In addition to the arguments set forth with respect to claim 148, neither Nagasawa *et al.* nor Taneja *et al.* teach or fairly suggest a method for the treatment of psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma in a human or animal, comprising administering an effective amount of a composition comprising three boswellic acids selected from the group consisting of: β-boswellic acid of 14 to 65% by weight, acetyl-β-boswellic acid of 5 to 65% by weight, 11-keto-β-boswellic acid of 5 to 60% by weight and acetyl-11-keto-β-boswellic acid of 5 to 60% by weight, wherein the % by weight is based on the total weight of the composition, as claimed in claim 191.

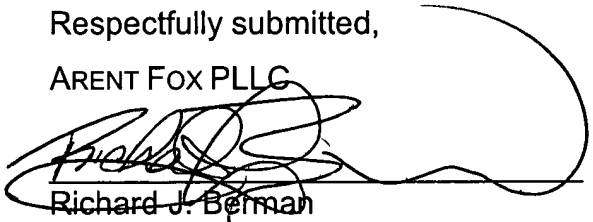
X. CONCLUSION

The appellants respectfully submit that the subject matter of claims 148 to 151, 175, and 177 to 191 is fully described in, and supported by, the specification under 35 U.S.C. §112, first paragraph and respectfully request the Honorable Board to reverse this rejection.

Further, the appellants respectfully submit that Shao *et al.* is not available as a reference under 35 U.S.C. §102 and that claims 148 to 151, 175, and 177 to 191 are not unpatentable over Nagasawa *et al.* in view of Shao *et al.* under 35 U.S.C. §103(a) and over Taneja *et al.* in view of Shao *et al.* under 35 U.S.C. §103(a). The appellants respectfully request the Honorable Board to reverse this rejection.

Respectfully submitted,

ARENT FOX PLLC



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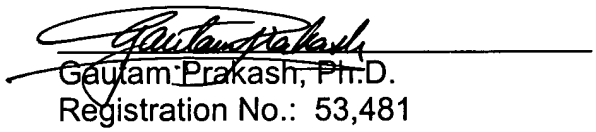

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XI. APPENDIX: COPY OF THE CLAIMS INVOLVED IN THE APPEAL

Claim 148. A method for the treatment of an autoimmune disease in a subject in need of the treatment, comprising a step of administering an autoimmune disease treatment effective amount of a composition to said subject, wherein the composition comprises

β-boswellic acid of at least 5% by weight,

acetyl-β-boswellic acid of at least 5% by weight,

11-keto-β-boswellic acid of at least 15% by weight and

acetyl-11-keto-β-boswellic acid of at least 14% by weight,

wherein said subject is a human or animal.

Claim 149. The method of claim 148, wherein the composition comprises

β-boswellic acid of at least 12% by weight,

acetyl-β-boswellic acid of at least 5% by weight,

11-keto-β-boswellic acid of at least 15% by weight and

acetyl-11-keto-β-boswellic acid of at least 14% by weight.

Claim 150. The method of claim 149, wherein the composition comprises

β-boswellic acid of at least 12 to 35% by weight,

acetyl-β-boswellic acid of at least 5 to 35% by weight,

11-keto-β-boswellic acid of at least 15 to 45% by weight and

acetyl-11-keto-β-boswellic acid of at least 14 to 45% by weight.

Claim 151. The method of claim 148, wherein the autoimmune disease is psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma.

Claim 175. A method for the treatment of an autoimmune disease in a subject in need of the treatment, comprising administering an autoimmune disease treatment effective

amount of a composition to said subject, wherein the composition comprises acetyl-11-keto-β-boswellic acid, and wherein said subject is a human or animal.

Claim 177. The method of claim 148, wherein said subject is a human.

Claim 178. The method of claim 175, wherein said subject is a human.

Claim 179. A method for the treatment of an autoimmune disease in a subject in need of the treatment, comprising administering an autoimmune disease treatment effective amount of a composition to said subject, wherein the composition comprises three boswellic acids selected from the group consisting of

β-boswellic acid of 14 to 65% by weight,
acetyl-β-boswellic acid of 5 to 65% by weight,
11-keto-β-boswellic acid of 5 to 60% by weight and
acetyl-11-keto-β-boswellic acid of 5 to 60% by weight,

wherein said subject is a human or animal, and wherein the % by weight is based on the total weight of the composition.

Claim 180. The method of claim 179, wherein the composition comprises three boswellic acids selected from the group consisting of

β-boswellic acid of 14 to 55% by weight,
acetyl-β-boswellic acid of 10 to 55% by weight,
11-keto-β-boswellic acid of 5 to 50% by weight and
acetyl-11-keto-β-boswellic acid of 5 to 50% by weight.

Claim 181. The method of claim 180, wherein the composition comprises three boswellic acids selected from the group consisting of

β-boswellic acid of 14 to 35% by weight,
acetyl-β-boswellic acid of 10 to 35% by weight,
11-keto-β-boswellic acid of 5 to 40% by weight and
acetyl-11-keto-β-boswellic acid of 5 to 40% by weight.

Claim 182. The method of claim 179, wherein the composition comprises three boswellic acids selected from the group consisting of

β-boswellic acid of 14% by weight,

acetyl-β-boswellic acid of 5% by weight,

11-keto-β-boswellic acid of 5% by weight and

acetyl-11-keto-β-boswellic acid of 60% by weight.

Claim 183. The method of claim 180, wherein the composition comprises three boswellic acids selected from the group consisting of

β-boswellic acid of 14% by weight,

acetyl-β-boswellic acid of 10% by weight,

11-keto-β-boswellic acid of 5% by weight and

acetyl-11-keto-β-boswellic acid of 50% by weight.

Claim 184. The method of claim 181, wherein the composition comprises three boswellic acids selected from the group consisting of

β-boswellic acid of 14% by weight,

acetyl-β-boswellic acid of 10% by weight,

11-keto-β-boswellic acid of 5% by weight and

acetyl-11-keto-β-boswellic acid of 40% by weight.

Claim 185. The method of claim 179, wherein the subject is a human.

Claim 186. The method of claim 180, wherein the subject is a human.

Claim 187. The method of claim 181, wherein the subject is a human.

Claim 188. The method of claim 182, wherein the subject is a human.

Claim 189. The method of claim 183, wherein the subject is a human.

Claim 190. The method of claim 184, wherein the subject is a human.

Claim 191. The method of claim 179, wherein the autoimmune disease is psoriasis, sarcoidosis, systemic lupus erythematosis, Grave's disease, Hashimoto's thyroiditis, silent thyroiditis, Crohn's disease, Goodpasture syndrome, insulin-dependent diabetes mellitus, insulin-resistant diabetes mellitus, myasthenia gravis, Addison's disease, idiopathic hypoparathyroidism, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, rheumatoid arthritis or scleroderma.